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EU governance and national responses in healthcare

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Synopsis

This contribution examines the increased European Union (EU) regulation within the healthcare sector, exemplified by the regulation of patient rights in cross border healthcare. This provides an example of the various complexities arising from the operationalization of a European Union policy within nation states' health systems. The contribution first analyses the judicial and political process through which patient rights in cross border health care became part of the EU regulatory competences, resulting in the adoption of the patient rights directive. The principles and content of this directive are found to be the most important regulatory piece of healthcare regulation within the EU to date. The contribution then examines the different set of challenges that EU healthcare governance introduces to the different healthcare systems of the Community. Thirdly, it analyses these challenges in two selected member states; the universalist and national healthcare system of Denmark and the insurance based healthcare system of Bulgaria. The two cases are selected because they vary in respect of on healthcare models as well as health care packages, spending, degree of centralization and administrative capacity among other factors.

Introduction

Healthcare as a public policy has traditionally been governed exclusively by the nation state. As a policy area it belongs to the core of the welfare state. How to organize healthcare, which healthcare coverage to provide, how to prioritize and so forth are key themes in national elections and an essential link in the social contract between the state and its citizens. Healthcare has developed in relative isolation as a result of domestic politics and actors (Greer 2009: 1). The national isolation of healthcare has, however, been increasingly disturbed by the integration dynamics of the European Union. The meeting between national health policy and EU law marks tensions and contradictions:

> 'Health care policy in the European Union has, at its centre, a fundamental contradiction. On the one hand, recent Treaties, which are the definitive statements on the scope of European law, state explicitly that health care is a responsibility for Member States. On the other hand, as health systems involve interaction with people (staff and patients), goods (pharmaceuticals and devices) and services (health care funders and providers), all of whose freedom to move across borders is guaranteed by the same Treaty, it is increasingly apparent that many of their activities are subject to European law' (Mossialos et al. 2001, p. 11).

For long, the right to cross border healthcare was governed by Community regulation 1408/71.[1] This regulation granted Community workers and later European citizens the right to acute healthcare treatment in another member as well as more limited access to planned healthcare treatment where the costs of care would be paid by the home member state (Martinsen 2009: 794-795; Palm and Glinos 2010: 514-515). The access to planned treatment in another member state was, however, firmly controlled nationally through the governing principle of 'prior authorisation'. According to this principle, a patient would have to be authorized beforehand by the competent national institution to have planned treatment in another member state. This implied that in reality few patients planned cross border treatment as authorization was seldom issued (Martinsen 2007:14).

Since the European Court of Justice in 1998 laid down that health care is not an ''îlot impermeable a l'influence du droit communautaire'[2], judicial interpretation of internal market principles and the subsequent political process have challenged the national ability to control cross border care quite fundamentally.

This EU development and its potential impact on national healthcare systems will be examined below. For this purpose, the contribution first presents the judicial process where the European Court of Justice applied internal market principles to the healthcare sector, then sets out the political negotiations leading to the Patient Rights Directive. The subsequent sections examine the content and overall implications of this Directive, how EU governance challenges the national healthcare systems in two selected member states; Denmark and Bulgaria, and how these two member states have initiated transposition of the Directive.

With the European Court towards EU healthcare regulation

In 1998, the European Court of Justice came out with two controversial rulings, laying down that health care is a service within the meaning of the Treaty, thus in principle to circulate freely.[3] Health ministers were upset, arguing that the rulings had to be overturned by a Treaty amendment.[4] Such Treaty amendment was, however, never adopted. In the end, Member States did not prioritize the matter sufficiently when negotiating the Treaty of Nice, and a Treaty clarification exempting health care from the internal market was not inserted (Martinsen and Falkner 2011).

This initial outburst was then later met by significant silence and a long period of no EU initiative. The Member States evidently waited for the Commission to come up with a proposal, which took a long time to prepare. In the meantime, the European Court of Justice went further in its interpretations on patients' rights and cross border health care. Its reasoning in a number of cases implies that for the wide scope of non-hospital care, a patient can go to another member state without authorisation from his/her home state, pay for the cost of treatment up front and subsequently have the costs reimbursed back home – up to what a similar treatment would have cost in the home member state.

Initially only the impact on social insurance systems was interpreted. National health service systems continued to argue that the rationale and reasoning of the Court cases did not apply to their systems as they are genuinely different, with limited elements of private pay and healthcare provided as benefit in kind. However, in the 2006 *Watts* case[5], the Court for the first time considered the implications for national health services. The Court concluded that the internal market principle applies to all healthcare

systems, irrespective of how they are financed or how they provide healthcare. The Court also stated that patients have a right to cross border treatment if the waiting-time for a similar treatment in their own member state exceeded what is acceptable.

In the 2007 case of *Stamatelakis*[6], the Court ruled that a member state cannot exclude reimbursing treatment in another member state on the grounds that it is provided in a private hospital. In the case, the Greek government submitted that the balance of the system is at risk if citizens can travel to private hospitals in EU countries without Greece having established agreements with those hospitals. However, these concerns were ruled out by the Court, which instead clarified that the Greek ban on reimbursement for private healthcare abroad is against Community law.

With this line of case law it took the European Court of Justice less than 10 years to apply internal market principles to national healthcare systems, disregarding how they are organized, financed or provide healthcare. Judicial decision-making had thus made a rapid intervention in a public policy domain once governed exclusively by national politics and protected by national borders.

Political negotiations on patient rights in cross border healthcare

The first attempt to respond to the Court's rulings came when the Commission, rather unsuccessfully, attempted to integrate the health care area in the Bolkestein Directive on services in the internal market, inserted in the Commission's proposal as an article 23.[7] The health ministers, however, were alarmed to have their policy area regulated as part of a general Directive on services, placed under the responsibility of DG Internal Market. Article 23, and thus the health care area, was taken out of the Directive.

Consequently it appeared clear that European health care could not be regulated from an overall internal market perspective, but the case law of the Court still called for a political response. The case law had disturbed the traditional national demarcation of healthcare policies, there was a need to reestablish legal certainty. After considerable preparatory steps, expert considerations and a failed attempt to present a proposal back in December 2007, the Commission finally proposed its directive on the 2 July 2008 on patient rights in cross border healthcare.[8]

The subsequent negotiation process became tense, ripe with conflicts on different dimensions of the proposal. The Council of Ministers had great difficulties in establishing a common position between the member states. Only 2-3 member states were in favour when the proposal was first presented by the Commission (A. Vassillou, 2980th meeting, Press Conference, 1st December 2009). A significant number of Ministers expressed concerns about national sovereignty, and wished to tighten national control in cross border care by means of prior authorization. Especially southern European nations expressed concerns, and in December 2009 Spain led a blocking minority against the Swedish Presidency compromise text, and the Council thus failed to reach an agreement. However, during 2010 disagreements were eased. In the second reading, a qualified majority was established in the Council but Austria, Poland, Portugal and Romania voted no and Slovakia abstained. The European Parliament also had difficulties in establishing a majority position. The Christian Democrats (EPP) and the Liberals (ALDE) were generally in favour of the Commission's proposal, but the Alliance of Socialists and Democrats (S&D) was divided internally on various issues, especially on the fundamental question of the correct legal base for the Directive and the issue of

prior authorization. However, gradually a compromise was established and by March 2011 the Directive was adopted by both institutions. The adopted text differs from the original proposal by the Commission on several aspects. A dual legal basis has been reached. The internal market legal base Article 114 TFEU constitutes the main legal basis, but Article 168 TFEU (on public health) has also been inserted. Another significant compromise is that prior authorization is accepted as the means of national control, but only allowed for care subject to planning; that is hospitalization or healthcare being highly specialized or implying cost-intensive medical infrastructure or equipment.

The process which finally reached a compromise on patient rights in cross border care substantiates that it took the representatives of the welfare states in the Council and a considerable part of European Parliamentarians quite some time to accept that health care falls under the rules of the internal market. The politicians managed to negotiate some exemptions to the general rule of free movement, but the process also substantiates that despite such political reservations, it is now a European binding norm that health care constitutes a service within the meaning of the Treaty, with all its implications. The principles and content of the Directive are substantial, with impact for all member states albeit depending on the national health system in place.

Content and overall implications of the patient rights directive

Among the 22 articles of the directive, at least seven appear to challengethe established status quo of national healthcare provisions across the EU, albeit to different degrees and to varying extent across the member states.

Article 4 establishes that where member states may be providing treatment they are obliged to ensure that *national contact points* provide patients with the relevant information on the standards of national healthcare (article 4.2.a). Member states are also responsible for ensuring that *healthcare provi*ders provide the relevant information for patients to make an informed choice on treatment options, availability, quality and safety and that the providers have clear invoices and clear information on prices, among other aspects (article 4.2.b).

Article 5 obliges the home member state (i.e. the member state where the patient is insured) to ensure that there are mechanisms in place to inform patients about their rights and entitlements in relation to cross border healthcare, conditions for reimbursement of costs as well as information on appeal and redress. Article 6 lays down that member states shall establish one or more national contact points. National contact points shall facilitate the exchange of relevant information regarding health services (article 6.2).

Article 7 establishes the principles of reimbursement of the costs of cross border care. Member states are obliged to 'to have a transparent mechanism for calculation of costs of cross-border healthcare that are to be reimbursed to the insured person by the Member State of affiliation. This mechanism shall be based on objective, non-discriminatory criteria known in advance' (article 7.6).

Article 8 deals with the issue of prior authorization, one of the most controversial issues in the case law and during the negotiations on the directive. De facto it lays down a distinction between three types of

healthcare services; *hospital care*, *highly specialized and cost-intensive care*, and *non-hospital care*. For hospital care as well as highly specialized and cost-intensive care prior authorization may be justified whereas it is not for non-hospital care. Prior authorization may not be refused if the requested healthcare cannot be provided in the member state of affiliation 'within a time limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, the degree of the patient's pain and/or the nature of the patient's disability at the time when the request for authorization was made or renewed' (article 8.5). The member state of affiliation shall make publicly available which healthcare is subject to prior authorization (article 8.7).

Article 9 obliges the member states of affiliation to ensure accessible administrative procedures, based on objective, non-discriminatory criteria which are necessary and proportionate to the objective (article 9.1.). Member states shall also ensure that individual decisions are properly reasoned and capable of being judicially challenged (article 9.4). Finally, article 11 lays down mutual recognition of prescriptions, issued in another member state.

These 7 articles are likely to have considerable consequences for national healthcare governance, depending on national healthcare schemes and how member state authorities understand and comply with their responsibilities. They oblige member states to develop and make accessible information on key component of healthcare provisions; standards, quality, pricing, administrative procedures, exit rights. Accessible and transparent information becomes a public responsibility and member states will have to intervene in relation to healthcare providers, be they public or private, to make such available. This call for certain degree of centralization, where the national governance level supervise that the obligations are complied with.

The implications of these seven articles are manifold. Below we will examine how the principles and content of the directive challenge two different healthcare systems represented by the Danish and Bulgarian member states, first from an overall institutional perspective, then by presenting in brief the first phase of transposition in these two rather different member states.

National healthcare systems and European governance

Albeit there are no two identical healthcare systems, the European health polities can roughly be divided in two distinct families. On the one side the universalistic, tax financed Beveridge model, also known as National Health System (NHS); and on the other the corporatist, social insurance contributions based Bismarckian system, or Health Insurance System (HIS) (Neergaard, 2011, p. 20). These two families differ on key characteristics which are of crucial importance for the successful implementation of the Directive. Of specific importance to the implementation of the directive are: 1) the level of centralization of the health system, i.e. which institution or governance level are responsible for the supply of healthcare, 2) the financing principles and the importance of out-of-pocket payments (OPPs), 3) the presence of defined benefits package and clear pricing of medical services as well as 4) governance principles in relation to the effectiveness and quality of the healthcare sector. The two cases selected for this study differ on all of these criteria and this is the reason they have been selected.

One of the most striking distinctions between the Danish and the Bulgarian cases is the level of centralization found in the two systems. Whilst the Bulgarian system is under the unconditional monopoly of the National Health Insurance Fund (NHIF), a semi-public, non-profit organization charged with the payment of services procured by Bulgarian insurance carriers from healthcare providers (Dimova et al., 2012, p. 55), the Danish system is considerably more decentralized. Healthcare in Denmark is a shared responsibility between the state, the five regions and the 98 municipalities. Within this power equation the state is mainly responsible for legislation, the regions for organizing and delivering services, whereas the municipalities have the responsibility for a number of prevention and rehabilitation services (Martinsen & Vrangbaek, 2007, p. 173). The decentralization of the Danish system means that there is a political environment in which the implementation of the Directive is in the hands of significantly more actors, than in the Bulgarian system. This is likely to lead to complications and impediments.

Secondly, the Danish and the Bulgarian systems differ in the ways in which healthcare services are financed and supplied. The Danish healthcare scheme is tax financed, providing universal public health service for all residents. The Bulgarian compulsory social insurance scheme is financed by contributions from Bulgarian citizens and from residents in Bulgaria and a scheme funded by taxes providing benefits in kind, other than those provided by the contribution-funded scheme.

In addition, the amount of 'Out of Pocket Payment' (OPP) differs greatly between Denmark and Bulgaria.Here it must be underlined that these come under various forms, from complementary payment for services which are not fully covered, through user fees and ultimately to 'under the table payments'. Our data does not give us a direct inside into the individual forms of OPP but they are clearly a lot lower in Denmark than in Bulgaria. In Denmark their figure stands at 14% of the total current health expenditure for 2008 (latest available data) whereas in Bulgaria it is as high as 42% (source Eurostat, 2013). The data from Eurostat is based on national statistical and administrative sources reflecting the national characteristics of the health system, which means that they may not be completely comparable. Nevertheless, what is certain, is that the Danish NHS system operates at much lower levels of OPP in the financing of healthcare, whereas OPPs are a highly important financing source in Bulgaria. Ultimately the OPPs 'reflect a scarcity of resources in the health care system' (Balabanova & McKee, 2002, p. 269). Especially informal payments have severe consequences on the effectiveness of the system, because the flow of resources into the system in part depends on the willingness and need of patients to make informal payments (Dubois & McKee 2004: 49-50). Budgetary transparency, capacity planning and equity are difficult to uphold in a system that in part relies on informal payments. OPPs, including informal payments, could potentially play a crucial role in the utilization of the Directive by the Bulgarian patients pushing them further towards taking advantage of the Directive in order to circumvent informal payments. In addition, the issue of wide-spread OPPs in Bulgaria could prove prohibitive to foreign patients who are unaware of more informal practices. The informal procedures of the Bulgarian system are likely to be challenged by the Directive's article 9, laying down that the Member State of affiliation shall have accessible and transparent administrative procedures, which are accessible to judicial redress. This highlights the importance of functioning complaints procedures as these will be particularly important for safeguarding patients' rights and by extension for the successful implementation of the directive.

A third distinction between the two systems stemming from their basic characteristics as NHS or HIS is the existence of specified benefits packages. HISs must provide a clear list of services which will be covered so

health providers within the system operate with a pre-defined benefits packages, whereas their NHS counterparts are more free to choose the services they can offer. In Denmark, the lack of clear benefits packages is also a result of the decentralization of the system and the lack of clear division of responsibilities. The 2007 Health Act which delegated the responsibility for the medical care of each patient to the regions, and the preventive services aimed at the general population and for rehabilitation and home care for patients to the municipalities, puts no one actor in charge of preparing the benefits package (Olejaz et al., 2012, p. 62). When it comes to the presence of clearly defined prices the two countries operate with different systems. Determined prices are a direct consequence of the precise benefit package in Bulgaria. In the Danish system, prices are calculated in the basis of DRG (Diagnosis Related Groups) prices, set between the regions and the national healthcare providers.

Finally, the governance principles in relation to the effectiveness and quality of the healthcare sector differ. In Denmark, the 'family doctor', i.e. the General Practitioner (GP) serves as an important gatekeeper for healthcare treatment and has been regarded as important for the quality of care, bridging patients demands and system supply. The GP thus has a most important control function in the Danish system, including access to pharmaceuticals by means of prescriptions, referring patients to specialist treatment and hospital care, ensuring continuity of care, providing information on care among other factors. In carrying out these tasks, the GP has an equally important function for the system, controlling healthcare expenditures. The GP refers all patients insured in group 1 to specialized care and all patients to hospital care. The group 1 insured will not be able to access specialized care, hospital care or prescribed medicine without the consent of the GP. A patient, once referred by the GP, has an extended free choice of hospital care if s/he cannot be treated within one month in his/her own region. In that case the patient can chose healthcare at a public hospital in another region or at a private or foreign healthcare provider with which the Danish regions have established an agreement beforehand. Thus currently waiting time for hospital care is set to be low by means of this extended free choice. The Danish NHS system thus currently operates relatively effectively, and the GP is regarded as an important gatekeeper for the quality of care. In Bulgaria the role of the General Practitioner is comparable to their Danish counterpart. The GP serves as an access point for incoming patients, assessing their overall health condition and evaluating the needs of patients for further medical treatment. In this sense the function of 'gatekeeper' is also to be found in the Bulgarian GP system, with one important addition. In order to receive specialized care (i.e. laboratory tests, inpatient care, specialist examination, etc.) patients need to receive a medical referral from their GP. The medical referral keeps the cost of specialized care under control, effectively eliminates long waiting times for patients, but it also aggressively restricts access to potentially life-saving treatments. This is due to the fact that the number of referrals is limited to the GPs, causing patients to wait because GP referrals are rationed. Referrals are rationed every month, meaning that a Bulgarian patient might have to wait more than a month to receive a referral from their GP. Without a referral the patient has to pay extra to receive the treatment, unless they also have voluntary health insurance[9] (which only covers a marginal portion of the population). The only specialized medical treatment for which no referral is required is dental care. In a situation where medical referrals become unavailable to the patients for a prolonged period of time this could lead to a situation where the Bulgarian state as the member state of affiliation under the provisions of the directive must provide prior authorization because it cannot provide medical treatment within a medically justified time period, i.e. without 'undue delay'. In this situation the directive would effectively extend the coverage of Bulgarian patients, simultaneously crippling the control the GPs provide.

The complex situation of Bulgarian GPs means that they will be practically inaccessible to foreign patients. GPs are very unlikely to give out referrals to foreigners as they need to keep their 'personal' patients supplied. This would almost completely eliminate the option of seeking specialized inpatient treatment in Bulgaria unless foreign patients are prepared to pay the full price of the treatment, in which case they still have to consider the potential reduced standards of quality under which it will be delivered.

Ultimately the cases of Denmark and Bulgaria represent maximum variations of the possible developments of healthcare systems within Europe. In the subsequent paragraphs we will examine how these variations are likely to influence the implementation of the Patients' rights Directive.

Transposing the patient rights directive

The patient rights directive is to be transposed by the member states by 25th October 2013. At the time of writing this contribution in early 2013, member states are still in full process of transposition for which reason it is only possible to draw out some overall challenges.

In Denmark, the Ministry of Health is responsible for the transposition of the Directive. The regions will however be responsible for the practical implementation of the Directive, when Danish patients request cross border care or foreign patients Danish care. The regions express their increasing frustration of not being closely involved in the transposition process which is said to be carried out in rather secluded manner by few civil servants in the Ministry of Health (Interviews November 2012). Especially the role of the contact points is found to be crucial but unclear. Contact points with high level of services are likely to lead to an enhanced inflow of foreign patients, whereas poor information is likely to limit de facto patient inflow and simultaneously increasing uncertainty. Key questions are still unanswered. How many contact points will have to be set up? Will they have to provide information in foreign languages? What willl be the extent and standard of information?

In Bulgaria for the overall monitoring of the actual implementation the competent institution is the Ministry of Labor and Social Policy. It follows the legislation prepared by the Ministry of Health in close partnership with the NHIF. The NHIF prepares concrete suggestions for the reform of functioning national legislation and after these suggestions are accepted by the Ministry of Health the process of transposition can begin in the National Assembly. On the issue of national contact points the Ministry of Health and the NHIF are passing responsibility between each other as to who would have to take over the establishment of these bodies. Since staffing the contact points requires people with language skills, knowledge of the normative statute and the intricacies of the national and international health systems, neither the Ministry nor the NHIF is willing to spare any of their staff to take on this new task (Interviews November, 2012). Concerning contact points, we already see how the resource unavailability of the Bulgarian system will start influencing the implementation in its early stages and is likely to lead to understaffing of the contact points and result in their inability to handle the workload.

Concerning the financing principles of the healthcare system, the limited OPP and no 'under the table payment' in Denmark limit the private economic motivation for patients to seek cross border healthcare.

As a NHS system, Danish public healthcare has not traditionally operated with clear patient rights and defined healthcare packages. The patient rights directive operates with a fundamentally different logic establishing a focus on patient rights, judicial redress and clear information on quality, standards and pricing. In this way, the governing principle of the EU directive is to enable the patient to carry out an informed choice and eventually exit from the national supply if not satisfied. The national authorities become responsible for proving the information and processes to facilitate both exits and inflow. In addition, 'clear pricing' is not straightforward for the Danish model. So far the Ministry of Health point to DRG prices as the natural level of price setting, turning to existing solutions (Interviews, August and November 2012). But representatives from the regions have pointed out that the DRG is a rather abstract means of price setting, not disaggregating the different components of a healthcare service, nor specifying when a healthcare treatment begins and ends (Ibid.). DRG prices might function in a national setting, where between regions and national healthcare providers have learned to trust this price mechanism, but in an internal market they hardly constitute transparent nor full prices (ibid.).

Prices of the medical services in Bulgaria are listed in the national framework contract, a record of all medical services offered in the Bulgarian system and covered by the NHIF. The framework contract however suffers from a central flaw – medical treatment prices in Bulgaria are drastically and inherently undervalued (Interviews November, 2012). This has to do with the fact that the entire system is underfinanced because of extremely low social insurance contributions. Although they represent 8 percent of the official income of employed people, the overall low level of payment in Bulgaria, the undocumented labour and other factors contributing to the 'shadow economy' leave the healthcare system necessitous and cash-strapped. A direct consequence is the aforementioned ubiquitous OPPs, where patients need to 'co-finance' their treatments. However the low prices of medical services in Bulgaria are unlikely to lead to increased medical tourism after the implementation of the directive. All accounts point out that medical tourism in Bulgaria is underdeveloped and a major impediment for it is the low quality of services (Interviews November, 2012). In addition the low pricing of services is sure to have a prohibitive influence on the cross border mobility of Bulgarian patients since the services they might acquire abroad will only be reimbursed to a very low level, due to the undervalued Bulgarian pricing.

Finally, the governance principles concerning effectiveness and ensuring quality of care are seriously disturbed by EU governance. At the moment, waiting times are generally relatively low in Denmark. Thus the Directive's principle that patients have a right to hospital, specialized and cost intensive care if care cannot be provided without undue delay is no immediate challenge to DK concerning Danish patients seeking cross border care. However, it may spur a considerable inflow of foreign patients. Some healthcare providers in DK may be highly attractive to patients in other member states due to effectiveness and quality of care. This will imply both challenges and new opportunities to a healthcare model, traditionally planning capacity strictly according to national demands. Furthermore, the Danish model of ensuring quality of care with the assigned 'family doctor', the GP, as gatekeeper is challenged. With the directive, a patient may ask a GP in a another member state for his/her opinion and advice and thus bypass the governance function that the GP has traditionally occupied. Also pharmaceuticals in other member states will be accessible by means of mutual recognition of prescriptions. The issue of pharmaceutical prescriptions is also expected to be problematic in Bulgaria as the country is the only one in the EU to use Cyrillic, effectively making its prescriptions a difficult read in the rest of the Union. The GP control function in the Danish model is thus in question and enhance de facto cross border care. Also doctors as a profession will be met by increased

demands of Europeanization to which they will have to adapt. This includes linguistic challenges, the demand and expectation of foreign medical practices and high mobility patients who can question doctors' assessment abroad.

Conclusions

The structural differences between the two systems presented here result in different conditions in which the directive must be implemented. These conditions effectively build two different environments in which the identical text of the directive is sure to have differing implications.

In the Danish case the lack of clear pricing and benefits packages will make the practical implication of the directive particularly difficult for the Danish authorities. The directive is also likely to challenge the control that the GP ensures over the system as patients will have access to European general practitioners. These issues will introduce challenges to the planning and execution of the Danish system, depending on the size of mobility. If patient mobility maintains its character of a marginal phenomenon, largely limited to the border regions (Baeten, 2012, p. 26) its effects in Denmark are likely to be negligible. At first sight, high quality of care and relative efficient treatment, i.e. low waiting lists, are likely to cause an inflow of foreign patients to the Danish system. However, if waiting times extend and limited quality are highlighted by European comparisons, the Danish system could face more Danish patients opting for treatment abroad. Both patient inflow and outflow could lead to pressure on the delivery of care, as capacity planning would become more difficult. Danish taxpayers would have to carry the additional administrative costs of foreign patients' entry into the Danish system as well as reimbursing procedures executed on Danish patients abroad.

In Bulgaria the overall low level of income is likely to cripple any of the benefits that the directive could provide. Since the directive covers expenses only to the point of coverage in the state of affiliation medical treatment abroad under the directive's provisions will be near to impossible for the majority of the Bulgarian population. Since medical services in Bulgaria are generally undervalued, this makes their pricing drastically lower in Bulgaria, and it means that the difference between the price covered by the NHIF and the price charged abroad would have to be paid by the patient. The directive is furthermore dwarfed in its influence by the functioning of Regulation 883/2004 which stipulates complete coverage of any medical treatment as long as it is offered by the state of affiliation and prior authorization has been issued. Thus for the Bulgarian patient, the Regulation is certainly the more attractive alternative.

The differing degree of centralization in both health polities is likely to be an advantage in the Bulgarian case as it operates with a reduced number of veto players and concentrates the transposition and implementation tasks within very few central institutions. We have seen the issue of national contact points cause friction between two of these institutions, but the close communication between them is likely to facilitate a compromise on this issue. In the Danish case, the attempt to concentrate the implementation procedures within the Ministry of Health has caused some frustration to the regions, who will be responsible for the practical implementation of the Directive.

The distinction drawn here between Denmark and Bulgaria, highlighting the main organizational features of the systems, accentuates the difficulties the national executive and policy makers face in the course of

implementation of the directive on cross-border patients' rights. Although all of the member states are implementing the same legislative text, the domestic resources and institutional particularities of healthcare systems will lead to distinctive impediments and specific member state challenges. This means that further implementation analysis will need to pay closer attention to the existing national institutional environment, the actors within and around these and the challenges that it is predisposed to cause in the course of implementation.

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[1] Regulation (EEC) No. 1408/71 of the Council of 14 June 1971 pertains to the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community. The regulation was substantially reformed with the adoption of Regulation 883/2004, adopted 29th April 2004.

[2] As formulated by the advocate general Tesauro in the 1998 cases of *Decker* and *Kohll*.

[3] In the cases C-120/95 Decker [1998] ECR I-01831 and C-158/96 Kohll [1998] ECR I-01931.

[4] See for example the reaction of the former German health minister Seehofer (Der Spiegel 1998 17/98, Fokus from May 1998).

[5] Case C-372/04, Watts, 16 May 2006.

[6] Case C-444/05, *Stamatelaki*, [2007], ECR I-3185.

[7] Proposal for a Directive of the European Parliament and of the Council on services in the internal market, COM (2004) 2.

[8] Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care, COM (2008) 414.

[9] Usually the voluntary health insurance only covers a portion of the medical cost. This depends entirely on the kind of premium owned by the patient. Unlike the statutory health insurance voluntary insurance does not cover dependents (i.e. spouses and children).